

In the Federal Register of January 12, 2000 (65FR1776), the Food and Drug Administration (FDA) published a final rule removing the provision for submitting Type I drug master files (DMFs). This rule is intended to eliminate submissions of information that are not necessary either to conduct inspections of manufacturing facilities or to review the chemistry, manufacturing, and controls sections of Investigational New Drug Applications (INDs), New Drug Applications, and abbreviated applications. The agency will no longer accept Type I DMFs or correspondence updating existing Type I DMFs.

The Center for Biologics Evaluation and Research (CBER) believes that for certain biological products, such as gene therapy products, review of some information that has previously been submitted in Type I DMFs is necessary to assess their safety for use in clinical trials under IND. CBER will accept this information for such products in Type V Master Files. On July 10, 2000, the effective date of this final rule, CBER intends to administratively recategorize current Type I Master Files that are still needed to other Master File Types as appropriate. Applicants who have current approved applications that reference Type I DMFs transferred to Type V DMFs may notify the agency of this change in an annual report as provided in 21 CFR 601.12.

Below is a table containing the tracking number (BBIND), and name and address of the sponsor for those Type I Master Files that CBER does not intend to recategorize and will close. If a holder of a Type I Master File believes that the Master File should be recategorized, the holder may contact the Division of Manufacturing and Product Quality (DMPQ) (HFM-207), Office of Compliance and Biologics Quality, CBER, 1401 Rockville Pike, Rockville, MD 20852-1448. DMPQ may also be reached at 301-827-3031.

Type 1 Master Files to be Closed Effective July 10, 2000

BBIND		SPONSOR	SPONSOR'S ADDRESS		
81	MF1	PARKE-DAVIS WARNER LAMBERT PHARMACEUTICAL RESEARCH DIV		170 Tabor Rd	MORRIS PLAINS
279	MF1	SKF	1250 S COLLEGEVILLE RD	PO Box 5089	COLLEGEVILLE
1,107	MF1	BEECHAM	EXECUTIVE OFFICES	501 5th Street	BRISTOL
1,532	MF1	HOFFMANN-LA ROCHE, INC	340 KINGSLAND STREET		NUTLEY
1,585	MF1	GENENTECH, INCORPORATED	1 DNA WAY		SOUTH SAN FRANCISCO
1,631	MF1	AMF	MOREHEAD PATTERSON CENTER	689 Hope Street	STAMFORD
1,671	MF1	PARKE-DAVIS WARNER LAMBERT PHARMACEUTICAL RESEARCH DIV		170 Tabor Rd	MORRIS PLAINS
2,021	MF1	VENTREX	217 READ STREET	PO Box 9731	PORTLAND
2,149	MF1	REVLON HEALTH	RORER PHARMACEUTICAL CORPORATION	500 Washington Drive	FORT WASHINGTON
2,238	MF1	KARYON TECHNOLOGY	CHARLES RIVER BIOTECHNICAL SERVICES, INC	251 Ballardvale Street	WILMINGTON
2,598	MF1	PHARMACIA & UPJOHN	7000 PORTAGE ROAD		KALAMAZOO
2,714	MF1	CHAS RIVER BIOTECH	251 BALLARDVALE STREET		WILMINGTON
2,976	MF1	DUPONT	DIAGNOSTIC IMAGING DIVISION	331 Treble Cove Road	NORTH BILLERICA
3,148	MF1	OSTERREICHISCHES	INSTITUT FUR HAEMODERIVATE GES. M.B.H.	Industriestrasse 67	A-1220 VIENNA
3,220	MF1	FRESENIUS MEDICAL CARE, NORTH AMERICAN	TWO LEDGEMONT CENTER	95 Hayden Avenue	LEXINGTON
3,225	MF1	STOLLE RESEARCH	2964 STREET, ROUTE 42 SOUTH		LEBANON
3255	MF1	HOFFMANN-LAROCHE, INC	340 KINGSLAND STREET		NUTLEY
3,381	MF1	OROS INSTRUMENTS	715 BANBURY AVENUE		SLOUGH
4,183	MF1	SANDOZ LTD	PHARMACEUTICAL DIVISION	CH-4002	BASLE
4,479	MF1	CHARLES RIVER DIV OF WILMINGTON PARTNERS LP	251 BALLARDVALE STREET		WILMINGTON
4,830	MF1	GENSIA LABS, LTD	19 HUGHES		IRVINE
5,339	MF1	BACHEM CALIFORNIA	3132 KASHIWA STREET		TORRANCE
5,644	MF1	MERCK FROSST CANADA INC	PO BOX 1005	Pointe-Claire-Dorval	QUEBEC
5,655	MF1	UNISYN TECHNOLOGIES, INC	25 SOUTH STREET, SUITE E		HOPKINTON
5,717	MF1	NUTRITIONAL PRODUCTS GROUP, NEW ZEALAND DAIRY BOARD	NUTRITIONAL PRODUCTS GROUP	25 The Terrace P O Box 417	WELLINGTON
5,719	MF1	NUTRITIONAL PRODUCTS GROUP, NEW ZEALAND DAIRY BOARD	NUTRITIONAL PRODUCTS GROUP	25 The Terrace P O Box 417	WELLINGTON
5,720	MF1	NUTRITIONAL PRODUCTS GROUP, NEW ZEALAND DAIRY BOARD	NUTRITIONAL PRODUCTS GROUP	25 The Terrace P O Box 417	WELLINGTON
5,721	MF1	NUTRITIONAL PRODUCTS GROUP, NEW ZEALAND DAIRY BOARD	NUTRITIONAL PRODUCTS GROUP	25 The Terrace P O Box 417	WELLINGTON
7,126	MF1	Q-ONE BIOTECH LTD	TODD CAMPUS	West of Scotland Science Park	GLASGOW

FOR FURTHER INFORMATION CONTACT:

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1401 Rockville Pike, Rockville, MD 20852-1448,
301-827-0373.